UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte VIJAY R. BAICHWAL, JIANING HUANG, HAILING HSU, and DAVID V. GOEDDEL

Appeal No. 2005-1791
Application No. 09/758,003

ON BRIEF

Before ADAMS, GRIMES and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

VACATUR AND REMAND TO THE EXAMINER

Having reviewed the record in this appeal, we have determined that the rejections under both the written description and the enablement provisions of 35 U.S.C. § 112, first paragraph are not based upon the correct legal standards. Accordingly, we vacate[1] the rejections of record and remand the application to the examiner to consider the following issues and take appropriate action.

[1] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

Claims 1, 3, 5, 6, and 10-35 are pending. Of these pending claims, claims 28 and 35 are objected to for depending from a rejected claim. Accordingly, claims 28 and 35 are not before us for review. See e.g., Brief, page 1. Claims 1 and 3 are illustrative of the subject matter on appeal and are reproduced below:

1. A recombinant polynucleotide encoding a RIP-Thr^{514} polypeptide, said polypeptide comprising at least 10 consecutive amino acid residues of the amino acid sequence set forth as SEQ ID NO:2, which consecutive amino acid residues comprise the amino acid residue 514 (Thr) of SEQ ID NO:2, wherein the polypeptide is immunologically distinguishable from RIP-Ser^{514}.

3. An isolated or recombinant polynucleotide encoding a RIP-$ACA^{1540-1542}$ nucleic acid comprising at least 24 consecutive nucleotides of the nucleotide sequence set forth as SEQ ID NO:1, which consecutive nucleotides comprise nucleotides 1540-1542 (ACA) of SEQ ID NO:1, wherein the nucleic acid hybridizes with RIP-$ACA^{1540-1542}$ cDNA but not with RIP-$TCT^{1540-1542}$ cDNA.

The examiner does not rely on prior art.

GROUNDS OF REJECTION

Claims 1, 3, 5, 6, 10-27 and 29-34 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 1, 3, 5, 6, 10-27 and 29-34 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

DISCUSSION

Written Description:

According to the examiner (Answer, page 4), appellants' "claims are drawn to polynucleotides that comprise only small regions of the disclosed sequence, and thus can vary substantially in length and in composition." In this regard, the examiner finds (id.), "[t]he single required common feature among all of the claimed polynucleotides is that they encode a mutation at position 514 of the encoded polypeptide. This single amino acid is not sufficient to impart characteristic physical, structural, or functional features to the invention." In addition, the examiner finds (id.), "[t]he limitations of antigenic distinctiveness or the ability to hybridize to one sequence but not the other is not sufficient to evidence possession of a genus of related molecules." According to the examiner (id.), "[t]here is no function associated with such limitations and they impart no structural features to the encompassed molecules." Thus, the examiner concludes (Answer, page 5), "the claimed subject matter has not been described so as to reasonable [sic] convey to one skilled in the art that the inventors had possession of the claimed invention."

As set forth in University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)

> "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

There is no requirement, however, that the representative species be described in terms of their complete chemical structure. See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002), emphasis omitted, alteration original,

> the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

Therefore, the instant specification can describe the claimed genus of nucleic acids, per Eli Lilly, by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus."[2] Alternatively, the specification can describe the claimed genus of nucleic acids by describing a "representative number" of nucleic acids, where the representative species are described according to the standard of either Eli Lilly or Enzo.[3]

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[2] With reference, inter alia, to claim 1, appellants explain (Brief, bridging sentence, pages 3-4), "the required region of the encoded polypeptide [set forth, for example, in claim 1] is not 'only one amino acid', but one of the only ten possible decapeptides of SEQ ID NO:2 that includes residue 514 (Thr)." With reference to claim 3, appellants explain (Brief, page 4), "the required common region is limited to one of the only 22 possible 24-mers that include 1540-1542 (ACA) of SEQ ID NO:1." We also recognize Table 1 and Table 2 of appellants' which disclose "[e]xamplary RIP-Thr^{514} polypeptides having RIP-Thr^{514} binding specificity"; and "[e]xamplary RIP-ACA$^{1540-1542}$ polynucleotides having RIP-ACA$^{1540-1542}$ binding specificity," respectively.

[3] As appellants explain (Brief, page 4), in addition to requiring a "common region", a partial structure, "the encoded polypeptide [of, for example, claim 1] is functionally limited to those immunologically distinguishable from RIP-SER^{514}," and "the nucleic acid [of, for example, claim 3] is functionally limited to those which hybridize with RIP-ACA$^{1540-1542}$ cDNA but not with RIP-TCT$^{1540-1542}$ cDNA."

The examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in appellants' disclosure a description of the invention defined by the claims. In re Wertheim, 541 F.2d 257, 191 USPQ 90, 97 (CCPA 1976). The only analysis presented by the examiner on this record is an example of ipse dixit reasoning, resting on a bare assertion by the examiner. We find no reasoned analysis of the claimed invention consistent with the relevant legal standards. Accordingly, we vacate the rejection of claims 1, 3, 5, 6, 10-27 and 29-34 under the written description provision of 35 U.S.C. § 112, first paragraph, and remand the application to the examiner for further consideration.

Upon receipt of the administrative file, we encourage the examiner to take a step back and reconsider the claimed invention together with appellants' specification and the relevant legal precedent. If after having the opportunity to reconsider the issue of written description, the examiner believes that a rejection is necessary under this provision of 35 U.S.C. § 112, first paragraph, we encourage the examiner to issue an appropriate Office action setting forth such a rejection, using the proper legal standards and clearly setting forth the facts relied upon in support of such a rejection. We note, however, that any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

Enablement:

According to the examiner (Answer, page 5), while appellants' specification is provides an enabling description of "the polynucleotide of SEQ ID NO: 1 and for polynucleotides encoding SEQ ID NO: 2, [it] does not reasonable [sic] provide enablement for sequences comprising only fragments of the disclosed sequence." While the examiner recognizes (id.), "[t]he specification discloses that the polypeptide of SEQ ID NO: 2, which is encoded by the polynucleotide of SEQ ID NO: 1, is a kinase and binds molecules important in the transduction of TNF-related signals," the examiner finds (id.), "the specification does not provide guidance for using any polynucleotides that do not have this function, but are encompassed by the claims." More specifically, the examiner finds (id.) appellants' claims

> are broad because they encompass polynucleotides that are very different from the disclosed sequence. Any given embodiment need have only part of its sequence in common with the disclosed sequence, and the only feature that all embodiments of the invention are required to posses [sic] is a mutation encoding a single amino acid.

In our opinion, the rejection under 35 U.S.C. §112, first paragraph, is based on a series of conclusions asserted by the examiner rather than a fact-based, reasoned explanation as to why a person skilled in the art would not be able to make and use the claimed invention throughout its scope without undue experimentation. As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

> [w]hen rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a

> reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

On this record, the examiner did not perform the fact-finding needed in order to reach a proper conclusion of undue experimentation. The enablement requirement of 35 U.S.C. or § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk. A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting Wright, 999 F.2d at 1561, 27 USPQ2d at 1513).

Whether making or using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See e.g., In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); see also Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). As set forth in Wands,

> [f]actors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in In re Forman, [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted).

In this regard, we recognize the examiner's assertion (Answer, page 6),

> [f]or these reasons, which include the lack of knowledge about functions of encompassed polynucleotides encoding polypeptides structurally related to SEQ ID NO: 2 that do not have the same function, the one working example of SEQ ID NO: 2, the lack of direction or guidance for using polynucleotides comprising only small regions of SEQ ID NO: 1, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

In our opinion, these assertions are far from a fact-based, reasoned analysis of record. Instead, we find these assertions to represent the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained her initial burden of establishing a prima facie case of non-enablement. Accordingly, we vacate the enablement rejection, and remand the application to the examiner for further consideration.

Upon receipt of the administrative file, we encourage the examiner to take a step back and reevaluate whether the information set forth in the specification in conjunction with the relevant prior art enables one to make and use the claimed invention throughout its scope without undue experimentation. If the examiner finds a rejection is necessary, under this provision of 35 U.S.C. § 112, first paragraph, we encourage the examiner to issue an appropriate Office action setting forth such a rejection, using the proper legal standards and clearly setting forth the facts relied upon in support of such a rejection. We note, however, that any further communication from the examiner that contains a

rejection of the claims should provide appellants with a full and fair opportunity to respond.

SUMMARY

The rejection of claims 1, 3, 5, 6, 10-27 and 29-34 under the written description provision of 35 U.S.C. § 112, first paragraph is vacated.

The rejection of claims 1, 3, 5, 6, 10-27 and 29-34 under the enablement provision of 35 U.S.C. § 112, first paragraph is vacated.

We remand the application to the examiner for further consideration of the record in a manner that is consistent with the foregoing.

VACATED and REMANDED

Donald E. Adams)
Administrative Patent Judge)
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Eric Grimes) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
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Lora M. Green)
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